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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,797	02/27/2004	Patrick Miles	014US1	9437

7590 06/16/2006

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EXAMINER

SMITH, STEPHANIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/789,797	MILES ET AL.	
	Examiner	Art Unit	
	Stephanie Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>30 July 2004</u> . <u>28 May 2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on July 30, 2004 and May 23, 2005 were filed after the mailing date of the application on February 27, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 9, 15, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Koros et al (U.S. 5928139). Referring to claims 1 and 15, Koros et al. teach a distraction and retraction system for creating a corridor to the spine (see figures 1 and 4 and column 2, lines 43-47 and column 6, lines 42-53). Koros et al. further teach that the retractor system is received within the distraction corridor, where corridor is defined as a passageway, and the system has a plurality of blades simultaneously introduced into the corridor and are dimensioned to be simultaneously opened to create a corridor to the surgical site (see figures 1 and 4 and column 2, lines 65-67; column 3, lines 1-8 and lines 12-17; and column 4, lines 23-28). Referring to claim 4, Koros et al. teach a plurality of arm members integrally formed together with a respective one of

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said plurality of retractor blades (see figure 1 and column 5, lines 29-45), where any of the arms can be used as a handle. Referring to claim 9, Koros et al. teach that this apparatus is configured to access a spinal target site (see figures 4 and 5 and column 2, lines 43-45). Referring to claims 17 and 18, Koros et al. teach that when the retractor blades are introduced into the spinal area, at least one shim element, in this case a screw, is detachably engaged with at least one of the retractor blades (see figures 3 and 5 and column 3, lines 10-12).

Claims 1, 5-7, 12, 14-15, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (U.S. 2002/0010392). Referring to claims 1 and 15, Desai teaches a retraction system with blades that can be opened to create an operative corridor to the target site, the blades being comprised of the ablation catheter (see page 3, paragraph 59, page 4, paragraph 61, and page 8, paragraphs 118-120). Referring to claims 5 and 14, Desai teaches a system for cardiac ablation that includes a multi-electrode catheter (see page 4, paragraph 65). Referring to claims 6-7 and 19, Desai teaches a computer that controls the various functional components of the mapping unit, and the electrogram signals emanated from a tachycardia site of origin are detectable by the electrode array, and the arrival times of sensed electrical activity are used to map the origin of a tachycardia (see page 2, paragraphs 26-29). Further, Desai teaches instructing stimulation of the heart to pick up arrival times to determine the direction and origin of activity and map the activity (see page 5, paragraph 81). Regarding claim 12, the control unit includes a display to display an electrocardiogram of the muscle (see pages 3 and 4, paragraph 60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3, 8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al. in view of Weiner (U.S. 2003/0225405). Koros et al. teach the apparatus described above, but do not teach using a K-wire and at least one dilator to perform distraction. Weiner teaches using K-wire for distraction and further teaches that it is well known in the art to use K-wire for distraction (see page 1, paragraph 17). Weiner further teaches that the K-wires extend through clamp openings (see page 2, paragraph 17), the clamp being a dilator because it can dilate a cavity or orifice. A clamp is a desirable dilator because it is rigid and adjustable. Regarding claim 3, Koros et al. teach the shim element as described above. Therefore, it would

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have been obvious to one of ordinary skill in the art at the time the invention was disclosed to combine the distraction and retraction system taught by Koros et al. with a the K-wire and clamp because it is well known in the art and because it is adjustable yet provides support.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al in view of as applied to claim 2 above, and further in view of Desai. Koros et al. in view of Weiner teach the apparatus described above, but do not teach placing a stimulation electrode at the tip of the K-wire. Desai teaches placing stimulation electrodes at the end of a catheter array (see page 4, paragraphs 66-68). Desai teaches that these electrodes provide accurate guidance (see page 2, paragraph 24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was disclosed to combine the apparatus taught by Koros et al. in view of Weiner with the electrode taught by Desai in order to provide accurate guidance.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al. in view of Dietz (U.S. 6126660). Koros et al. teach the apparatus described above, but do not teach a lateral, trans-psoas approach. Dietz does teach a lateral, trans-psoas approach and that this is an approach used often (see column 10, lines 27-31). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to combine the apparatus taught by Koros et al. with using a lateral trans-psoas approach because it is common to use such an approach in distraction.

Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al. and Desai as applied to claim 6 above, and further in view of Dabney

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et al (U.S. 6620157). Koros et al. in view of Desai teach the apparatus described above, but do not teach the button on the handle to initiate stimulation or the touch-screen. Dabney et al. do teach the button on the handle to initiate stimulation or the touch-screen (see column 7, lines 1-13). A button on the handle allows the user to easily and quickly provide stimulation and the touch screen also allows a user to quickly and easily select options. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus taught by Koros et al. in view of Desai with a button to provide stimulation and a touch-screen in order to allow the user to quickly and easily perform therapy or select options.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRS 6/12/2006
SRS


GEORGE R. EVANISKO
PRIMARY EXAMINER

6/12/6